

REMARKS

Claims 35, 36, 39-42, 46 and 48 are all the claims pending in the application. Claims 37, 38, 43-45 and 47 have been canceled.

Claims 36 and 40 have been amended. Support for the amendments is described below.

I. Office Action Summary

Information Disclosure Statements

PTO Forms 1449 filed on January 16, 2004, and May 28, 2004, are still outstanding.

The Examiner has requested, respectfully, to review the references and return initialed and signed copies of these outstanding forms with the next communication.

II. Detailed Action

A) Claim Rejections - 35 U.S.C. § 102

Maytansinol claims 36, 40, 43 and 47 were rejected under 35 U.S.C. § 102(b) as being anticipated by Higashide, *et al.* (U.S. 4,151,042). The Examiner stated that the claims read on maytansinol. In addition, the Examiner stated that even though claims 40 and 47 require that the maytansinol is purified, the claims still read on maytansinol.

In the interest of expediting prosecution and solely in the interest of accommodating the Examiner's preference, Applicants have amended claims 36 and 40 and canceled claims 43 and 47.

The Teachings in Higashide, et al. Patent:

Higashide, *et al.* patent teaches a method for preparing a crude form of maytansinol from a microorganism requiring a carbon and a nitrogen source. See, for example, column 12, line 44, see also claim 1. Furthermore, Higashide, *et al.* purified the crude product to obtain 1.1 parts of

maytanacine, 2.2 parts of maytansinol propionate, and 0.1 part of maytansinol. See column 12, lines 45-47. Therefore, Higashide, *et al.* teaches a method of preparation of a complex in which the end product comprises a mixture of (i) maytanacine, (ii) maytansinol propionate, and (iii) maytansinol, of which maytansinol comprises only 0.1 parts.

The Teachings in Applicant's Application:

Contrary to the teachings of Higashide, *et al.*, Applicants have described a novel process for purification of maytansinol from unreduced or over-reduced maytansinoids.

Applicants' claims, as amended, are directed to isolated maytansinol that is at least 90% free of unreduced or over-reduced maytansinoids. The maytansinol produced by the Applicants' process is of greater purity (at least 90% maytansinol) and is much better suited for therapeutic use. With the amendments made, claims 36 and 40 include the language "at least 90% pure." Therefore, the amended claims conform to the invention as set forth in the specification and the terms and phrases used are supported in the description. For example, the Applicants have disclosed in the specification that "[P]referably, maytansinol (2) purified by this process is at least 90% pure, more preferably at least 95% pure. One of ordinary skill in the art will understand that if maytansinol (2) of less than 90% purity is used in the following steps, additional purification steps may be required." See column 10, lines 34-38.

B) Objection to Claims

In the middle of page 2, claims 44 and 45 were objected to as being substantial duplicates of claims 37 and 38, respectively.

In the interest of expediting prosecution, and in no way acquiescing to the Examiner's objection, Applicants have cancelled claims 44 and 45.

Amendment Under 37 C.F.R. §1.111
U.S. Application No. 10/758,264

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In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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